Appointment

From: Keigwin, Richard [Keigwin.Richard@epa.gov]

Sent: 9/27/2018 7:20:16 PM

To: Keigwin, Richard [Keigwin.Richard@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; McNally, Robert

[Mcnally.Robert@epa.gov]; Miller, Wynne [Miller.Wynne@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]

Subject: Vector Control Tools and Technologies

Attachments: Malaria elimination impact on productivity - handout - July 25 2018.pdf; Malaria elimination impact on income -

handout - July 25 2018.pdf; EPA IVCC Nov 6th meeting_Pre read.pdf; VERV-HlthAff-2017.pdf

Location: DCRoomPYS9100/Potomac-Yard-One

Start: 11/6/2018 7:00:00 PM **End**: 11/6/2018 10:00:00 PM

Show Time As: Tentative

Adding articles. From Nick Hamon's 8/22 email below:

For background, I have attached a pdf of my slides for the ACS conference talk I am giving here in DC tomorrow. I do briefly mention VERV. I think this slide set addresses some of the key challenges we face as a Product Development Partnership in keeping innovators engaged. I have also attached the 2016 IVCC annual report that gives a reasonable overview of what we are trying to achieve with the support of USAID/PMI, BMGF, UKAID, SDC and UNITAID. I do believe that a VERV could be transformational and represent a win-win for EPA, the ag company innovator and funders, but in particular for Global public health and malaria/NTD eradication.

Related emails below:

From: Nick Hamon

Sent: 18 September 2018 17:00

To: 'Jewell, Shannon' <jewell.shannon@epa.gov>

Cc: Lynn Byrne < Lynn. Byrne@ivcc.com >

Subject: RE: Thank you

Dear Shannon,

Many thanks for your patience. We have arranged a meeting with the PRIA Coalition from 10 am until noon on November 6th. Could we perhaps join you the afternoon of the 6th? I am assuming the PRIA Coalition meeting will be at the CLA offices on 15th St NW #400, Washington, DC., so we should be able to get to you easily after the meeting. I can work with Rick on an agenda and a list of participants

Kind regards

Nick

Nick Hamon Ph.D. CEO, IVCC Pembroke Place Liverpool L3 5QA

Tel: +44 (0) 151 705 3124 Fax: +44 (0) 151 705 3345 Mob: Ex. 6 Personal Privacy (PP)

nick.hamon@ivcc.com

www.ivcc.com



ZERO 40 TOGETHER WE CAN CHANGE THE WORLD.

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From: Jewell, Shannon < jewell.shannon@epa.gov>

Sent: 10 September 2018 18:01

To: Nick Hamon < nick.hamon@ivcc.com > Cc: Lynn Byrne < lynn.byrne@ivcc.com >

Subject: RE: Thank you

Absolutely Nick, thank you very much for the heads-up.

Shannon

Shannon Jewell · (703) 347-0109 · jewell.shannon@epa.gov

From: Nick Hamon [mailto:nick.hamon@ivcc.com]
Sent: Monday, September 10, 2018 12:58 PM
To: Jewell, Shannon@epa.gov>

Cc: Lynn Byrne < lynn.byrne@ivcc.com>

Subject: RE: Thank you

Many thanks Shannon. Let me just confirm times for the PRIA Coalition and also see what works best for the majority. I will try to get back to you this week if that is OK?

Kind regards

Nick

Nick Hamon Ph.D. CEO, IVCC Pembroke Place Liverpool L3 5QA

Tel: +44 (0) 151 705 3124
Fax: +44 (0) 151 705 3345
Mob: Ex. 6 Personal Privacy (PP)
nick.hamon@ivcc.com

www.ivcc.com www.zeroby40.com



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From: Jewell, Shannon < jewell.shannon@epa.gov>

Sent: 10 September 2018 17:45

To: Nick Hamon < nick.hamon@ivcc.com > Cc: Lynn Byrne < lynn.byrne@ivcc.com >

Subject: RE: Thank you

Hello Nick,

I'm happy to help you with this. Would you like to meet with Rick on the morning or afternoon of the 6th? The morning, 9am to 12pm, looks a bit better for the OPP team that Rick mentioned. The afternoon of the 5th November 2-5pm, as well as the afternoon of the 7th November, 1-4 would work on this end. If 3 hours seems too short, we can stretch it to 4 on any of these.

Thank you, Shannon

Shannon Jewell · (703) 347-0109 · jewell.shannon@epa.gov

From: Keigwin, Richard

Sent: Monday, September 10, 2018 10:49 AM **To:** Nick Hamon nick.hamon@ivcc.com

Cc: Lynn Byrne !ynn.byrne@ivcc.com; Jewell, Shannon jewell.shannon@epa.gov>

Subject: RE: Thank you

Nick-

Thanks for your note. Yes, let's try to meet when you are in town in November. Shannon Jewell can work with you to get something scheduled. I'd probably want to also have some of our division directors attend, including Mike Goodis (Director of the Registration Division), Bob McNally (Director of the Biopesticide and Pollution Prevention Division), and Wynne Miller (Director of the Biological and Economic Analysis Division). Ed Messina, the Acting Deputy Office Director, would probably attend, as well.

--Rick

From: Nick Hamon [mailto:nick.hamon@ivcc.com]

Sent: Monday, September 10, 2018 6:44 AM

To: Keigwin, Richard < Keigwin.Richard@epa.gov>

Cc: Lynn Byrne < lynn.byrne@ivcc.com>

Subject: RE: Thank you

Dear Rick,

Firstly, let me congratulate you on your appointment as Director of OPP. I hope this is working out well and you are getting all the support you need from the current administration.

We met in DC a year ago to discuss vector control and possible EPA support for a VERV. Since that time, a great deal has happened in IVCC. In May 2018, the Australian Department of Foreign Affairs and Trade awarded IVCC a five year grant to support their Indo-Pacific Health Security Initiative. This program is designed to contribute to the avoidance and containment of infectious disease threats with the potential to cause social and economic harms on a national, regional or global scale; health security at home as well as in neighbouring countries. IVCC will explore the use of its launched and pipeline of vector control tools in the Indi-Pacific region as well as for Australia's health security needs. Unitaid and the Global Fund to Fight Aids, TB and Malaria also awarded IVCC \$70m to support the introduction of novel dual active ingredients long lasting insecticide treated nets, including price support and field trials to assess performance and public health value.

It is clear that malaria eradication is going to need innovative partnership models as well as novel vector control tools and technologies. One example a new type of partnership is represented by ZERO by 40 (zeroby40.com). The CEO's of the major research based agrochemical companies gathered at the World Economic Forum in Davos back in January at a meeting hosted by Bill Gates and IVCC. Then, at the Commonwealth Heads of Government Meeting in London just three months later, these same companies made a public commitment on a world stage to work collaboratively to play their part in advancing vector control innovation, with a goal of eradicating malaria by the year 2040. ZERO by 40 formalizes the partnership between the leading crop protection companies and IVCC in vector control to help make continued progress in the fight to end malaria. As part of the ZERO by 40 initiative, IVCC has worked with Dr Derek Willis to understand the link between malaria eradication and smallholder agriculture in sub Saharan-Africa. I have attached two paper, one recently published and the second in press that demonstrate a very strong economic business case for malaria eradication based on the projected increase in agricultural productivity alone.

Dr Jeff Moe and Dr David Ridley (both Duke University and creators of the Priority Review Voucher) and a small team from IVCC plan to meet with the PRIA Coalition in DC on 6th November to discuss moving the VERV forward. As we discussed back in August 2017, I would very much appreciate the opportunity to meet with you and your team to provide an overview of the development pipeline of vector control products and to brainstorm about how we might work together to accelerate the development of new vector control tools to combat malaria and NTDs. If you can spare half a day, perhaps on the 6th November (or maybe another day that week), I can bring some key members of the IVCC team to meet you and the OPP team. This would allow us to take an in-depth look at the tools and technologies that may potentially play an important role in US and US military health security.

I hope you can work IVCC in to your busy schedule

Kind regards

Nick

Nick Hamon Ph.D. CEO, IVCC Pembroke Place Liverpool L3 5QA

Tel: +44 (0) 151 705 3124 Fax: +44 (0) 151 705 3345 Mob: Ex. 6 Personal Privacy (PP) nick.hamon@ivcc.com

www.ivcc.com www.zeroby40.com



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From: Keigwin, Richard < Keigwin. Richard@epa.gov>

Sent: 22 August 2017 21:49

To: Nick Hamon < nick.hamon@ivcc.com >

Cc: Lois Rossi Ex. 6 Personal Privacy (PP)

Subject: RE: Thank you

Nick-

Thanks for your very kind note. These college transitions are very interesting. We've been fortunate that both of our kids have stayed basically 2 hours away – we got very lucky!

Here is a boilerplate non-disclosure agreement that we have used in the past. If this is something that you'd like to pursue so that we can have a freer discussion on some of the work you are doing, we would ask that you take a stab at completing the attached. I can then have our Office of General Counsel review the agreement.

Looking forward to continuing to learn about the work you are doing.

--Rick

Rick Keigwin Acting Director, Office of Pesticide Programs US Environmental Protection Agency

From: Nick Hamon [mailto:nick.hamon@ivcc.com]

Sent: Tuesday, August 22, 2017 9:22 AM

To: Keigwin, Richard < Keigwin. Richard@epa.gov>

Subject: Thank you

Dear Rick,

Many thanks for taking the time to meet with me yesterday.

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Ex. 6 Personal Privacy (PP)

Thank you for the positive response to the VERV concept. I understand that back in 2006, when the PRV paper published, FDA were less than enthusiastic. Even with that underwhelming support, the PRV made it into law in about 12 months. Times have changed and there is now a general recognition that we are thin on vector control tools in the public health toolbox, and almost nothing for an emergency response. I am hoping that a VERV will incentivise the Fortune 500 ag companies to rethink their public health strategies and put vector control / pest control back on the R&D agenda. It is becoming increasingly hard to raise money to support the development of novel chemistry/modes of action targeted at vectors...and even if we have the funding many of the companies do not see a return on investment in a commodity market. In fact, even with a VERV it is hard turn the NPV for novel insecticide development positive.

For background, I have attached a pdf of my slides for the ACS conference talk I am giving here in DC tomorrow. I do briefly mention VERV. I think this slide set addresses some of the key challenges we face as a Product Development Partnership in keeping innovators engaged. I have also attached the 2016 IVCC annual report that gives a reasonable overview of what we are trying to achieve with the support of USAID/PMI, BMGF, UKAID, SDC and UNITAID. I do believe that a VERV could be transformational and represent a win-win for EPA, the ag company innovator and funders, but in particular for Global public health and malaria/NTD eradication.

I look forward to working with you on the next steps. On 15th September 2017 at the Duke University offices in Washington DC (1201 Pennsylvania Avenue NW, Suite 500) we have the 'launch' / press conference for the Vector Expedited Review Voucher initiative. David Ridley and Jeff Moe will be presenting. Unfortunately, I am away in South Africa but IVCC will be represented by Jason Richardson (ex. AFPMB).

Event Name: Policy Solutions for Health Innovation: New Proposals for Market-Based Incentives

Time, Location: September 15, 2017, 7:30 – 9:15 am

Duke in DC Large Conference Room

1201 Pennsylvania Avenue NW, Suite 500

Washington DC

Sponsors: Duke-Margolis Center for Health Policy

Duke Executive Education, Fugua School of Business

Objectives: Highlight Duke policy research

Audience: Congressional staffers associated with committees that influence health care and the

EPA

Fugua alumni in health care in the DC area

Prospective executive education students/companies

Event format: 7:30-8:00 Continental Breakfast & Networking (pre-function area)

8:00-9:15 Presentations and Q&A (large classroom)

Event flow (draft):

8:00 Welcome and Introductions

Mark McClellan, MD, PhD, Director, Duke-Margolis Center for Health Policy

Robert J. Margolis Professor of Business, Medicine and Health Policy

8:05-8:25 Economic Incentives for Antimicrobial Drugs

Mark McClellan, MD, PhD

Gregory Daniel, PHD, MPH, Deputy Director, Duke-Margolis Center for Health

Policy, Professor of the Practice, Fuqua School of Business

8:25-8:35 Q&A

8:35-8:55 A Voucher System to Promote a New Generation of Insecticides to Fight Vector-Borne Diseases

David B. Ridley, PhD, Dr. and Mrs. Frank A. Riddick Professor of the Practice of Business

Jeffrey Moe, PhD

Professor of the Practice, Global Health, Duke Global Health Institute

8:55-9:05 Q&A

9:05-9:15 Wrap up

Kind regards

Nick

Nick Hamon Ph.D. CEO, IVCC Pembroke Place Liverpool L3 5QA

Tel: +44 (0) 151 705 3124
Fax: +44 (0) 151 705 3345
Mob: Ex. 6 Personal Privacy (PP)
nick.hamon@ivcc.com

www.ivcc.com



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